REMARKS

Claims 1-11, 13, 15-17, 19, 22 and 27-29 are pending. Claims 12, 14, 18, 20-21, 23-26 and 30-50 were previously canceled without prejudice or disclaimer. See Item 13 of PTO-1390, dated February 20, 2002.

I. The Restriction Requirement and Applicant's Provisional Election

The Examiner required restriction, under 35 U.S.C. §§ 121, 372, between Groups 1 to 24 as these inventions or groups of inventions allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicants note that claims 12, 14, 18, 20-21, 23-26 and 30-50 were previously canceled without prejudice or disclaimer. See Item 13 of PTO-1390, dated February 20, 2002.

In response, Applicants hereby elect, **with traverse**, Group 2, claims 3-9 and 11 (claims 12 and 48 were previously canceled), drawn to DNA of SEQ ID NO:4 encoding HLYA-1, vector, host cells and a recombinant method of making the polypeptide.

II. The Polypeptides Of Group 1 And The Polynucleotides Of Group 2 Exhibit Corresponding Special Technical Features

Applicants traverse the restriction requirement because the unity of invention standard must be applied in national stage applications. Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides that

> when the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111 . . . .

. . .

> In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2 . . . .

MPEP at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage (filed under 35 U.S.C. 371) applications.

Id. at page 1800-149, col. 1.

Indeed, according to Example 17, Part 2 of Annex B to the PCT Administrative Instructions, the Examiner is obliged to find that "the protein and the DNA sequence exhibit corresponding special technical features" and that, therefore, there is no lack of unity between claims directed to a protein "X" and the DNA sequence that encodes protein "X."

Thus, in the present case, unity of invention does exist at least as between claims 1-2 and 16-17 of Group 1, which encompass the polypeptides of SEQ ID NO:1, and claims 3-9 and 11 of Group 2, which encompass in part the polynucleotides which encode those polypeptides. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-9, 11 and 16-17 of Groups 1 and 2, and examine those claims in a single application.

In particular, as Applicants argue below, it is respectfully requested that claims 1-2 and 16-17 of Groups 1, 3 and 5, which encompass the polypeptides depicted in SEQ ID NO:1-3, be rejoined with claims 3-9 and 11 of Groups 2, 4 and 6, which encompass the polynucleotides which encode those polypeptides.

III. In Accordance With Office Practice, The Examination Of Claims To Ten Polynucleotide Sequences Does Not Create An Undue Burden

Applicants draw the Examiner's attention to Section 803.04 of the Manual of Patent Examining Procedure. While contending that nucleotide sequences that encode different proteins "constitute independent and distinct inventions" the Commissioner has decided to "permit a reasonable number of such nucleotide sequences to be claimed in a single application" so as to "further aid the biotechnology industry in protecting its intellectual property." See id. To this end, the Patent Office "determined that normally ten sequences constitute a reasonable number for examination purposes" and that that number does not create "an undue burden on the Office." Id. Indeed, the Office states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Id. Accordingly, the Examiner's contention that Groups 2, 4 and 6 are "distinct from the other" and, therefore, subject to restriction, is not consistent with Office practice.

Indeed, under the "Examples of Nucleotide Sequence Claims" subsection of Section 803.04, the Office states that "[O]nly the *ten* nucleotide sequence selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom *will* be examined" (emphasis added).

For this reason, Applicants further traverse the restriction requirement. Applicants contend that Groups 4 and 6 (claims 3-9 and 11), drawn to the polynucleotides encoding the polynucleotides of SEQ ID NO:5-6, should be examined alongside the polynucleotides of Group 2. Accordingly, Applicants kindly request that the Examiner rejoin Groups 4 and 6 and examine together these three polynucleotides. Should Examiner Saidha maintain this restriction, Applicants would be grateful to learn of the Examiner's explicit reasons for deciding against this MPEP-suggested course of action.

IV. The Search Of Groups 1-6 Is Not Unduly Burdensome

Applicants also traverse the restriction requirement on the grounds that the search and examination of at least Groups 1, 3 and 5 and 2, 4 and 6 (Groups 2, 4 and 6 are drawn to polynucleotides encoding a protein comprising the amino acid sequences of SEQ ID NO:4-6 and Groups 1, 3 and 5 are drawn to the polypeptides of SEQ ID NO:1-3) is not unduly burdensome. According to MPEP section 803 "if a search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." As the polynucleotides of Groups 2, 4 and 6 encode the polypeptides of Groups 1, 3 and 5, Applicants suggest examination of at least Groups 1-6 can be made without serious burden.

In particular, as Applicants have elected Group 2, it is respectfully requested that claims 1-2 and 16-17 of Group 1 be rejoined with the claims of Group 2.

V. The Methods of Use Claims of Groups 10-12 Are Properly Examined With The Compositions Of Groups 2, 4 and 6

Applicants also traverse this restriction requirement on the grounds that the search and examination of at least Groups 3-12 and 64-73 (Groups 3-12 are drawn to, *inter alia*, proteins comprising the amino acid sequences of SEQ ID NO:3-12 and Groups 64-73 are drawn to methods of using the proteins of SEQ ID NO:3-12, or a fragment or variant thereof having at least 90% sequence identity thereto, in an assay to detect a compound that binds specifically thereto) is not unduly burdensome.

The traversal is on the grounds that it would not place an undue burden on the Examiner to search claims directed to a composition, such as claims 3-9 and 16-17 of Groups 2, 4 and 6, and claims directed to methods of using the composition, such as claims 13 and 15 of Groups 10-12. Applicants remind the Examiner that rejoinder of method claims of equal or narrower scope is required upon allowance a product claim, as provided in MPEP §

821.04. This is particularly relevant when, as in here, process claims "depend from or otherwise contain all the limitations of the patentable product." Id.

Since it is believed that the search and examination of at least Groups 2, 4, 6 and 10-12 is not unduly burdensome upon the Examiner, restriction is not proper and should be withdrawn. In particular, as Applicants have elected Group 2 drawn to the polypeptide reagent used in Group 10, it is respectfully requested that claims 13 and 15 of Group 10 be rejoined with the claims of Group 2.

VI. Conclusion

Applicants respectfully request withdrawal of the restriction requirement at least as to claims claims 1-9, 11, 13 and 15-17 of Groups 1-6 and 10-12, drawn to the isolated polypeptides of SEQ ID NO:1-3, to the isolated polynucleotides of SEQ ID NO:4-6, and to method of using the polynucleotides of SEQ ID NO:4-6.

In particular and in view of the election of Group 2, Applicants respectfully request rejoinder of claims 1-2 and 11 of Group 1, drawn to an isolated polypeptides of SEQ ID NO:1, and claims 13 and 15 of Group 10, drawn to methods of using the polynucleotides of SEQ ID NO:4, with claims 3-9 and 16-17 of Group 2, drawn to an isolated polynucleotide of SEQ ID NO:4 which encodes the polypeptide of Group 1.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should be charged to our Deposit Account.

Respectfully submitted,

Date August 2, 2004

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